

A randomised study to evaluate two different skin
closure techniques:
Subcuticular sutures vs. staples: An investigation into
patient satisfaction

by
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This dissertation is done according to the requirements of the MMED Obstetrics and Gynaecology at the University of Stellenbosch. This is my original work.

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ABSTRAK

Ewekansige studie van subkutane oplosbare steke teenoor metaal velhakies: ‘n Onderzoek na pasiënt tevredenheid van verskillende vel sluitings tegnieke.

NAVORSINGS DOEL

Die fokus van hierdie projek is om vas te stel wat die beste metode van vel sluiting is ten opsigte van pasiënt bevrediging ten opsigte van wond voorkoms en pyn.

METODES

Een honderd pasiënte is ewekansig verdeel tot velsluiting van abdominale wonde met subkutane oplosbare steke of velhakies. Evaluasie is gedoen tydens ‘n opvolg besoek 6 weke na chirurgie. Die hoof uitkoms was pasiënt tevredenheid. Evaluasie van wond komplikasies is as sekondêre uitkoms beskryf.

RESULTATE

Vroulike pasiënte wat ‘n Pfannenstiel velinsnyding ondergaan toon geen verskil in pasiënt tevredenheid wanneer subkutane steke ($n = 51$) met velhakies ($n = 49$) vergelyk word nie ($P = 0.76$).

SAMEVATTING

Ons projek het geen statisties beduidende verskil getoon ten opsigte van pasiënt tevredenheid of wond voorkoms met 6 weke opvolg nie. Dit laat dus die besluit

by die chirurg om metode van velsluiting te kies afhangend van voorkeur en toerusting beskikbaarheid.

ABSTRACT

OBJECTIVE

The purpose of the study is to establish the best method of wound closure with regards to patient satisfaction that includes wound cosmesis and pain.

STUDY DESIGN

One hundred patients were randomised to two groups for the closure of abdominal wounds; one group had subcuticular sutures and the other staples. They were followed up at 6 weeks. The primary outcome was patient satisfaction that includes wound cosmesis and pain. The secondary outcome was wound complications.

RESULTS

In women undergoing abdominal operations there was no difference as regards the patient satisfaction in both the groups, subcuticular sutures $n=51$ vs. staples $n=49$ ($P = 0.76$).

CONCLUSION

Our study suggest that there is no statistically significant difference in the methods of wound closure, subcuticular sutures vs. staples as regards the patient satisfaction and the appearance of the scar leaving the decision in the hands of the surgeon to choose any method according to their own personnel preference and availability.

INTRODUCTION

Every year several million women have to undergo gynaecological surgery. As a result of that they acquire an abdominal scar. Nowadays women of all ages place extreme importance on the appearance of the scar in addition to the symptoms of pain, tenderness and itching. An aesthetically poor scar can have a negative impact on the overall quality of life causing considerable distress, loss of self-esteem and unhappiness. [1, 2] The appearance of the scar is of significant importance and is often the only reminder of surgery.

The outcome of the surgical skin closure is influenced by the indication for the procedure, the location of the surgical site and the associated intra-operative or post-operative complications. The general medical condition of the patient is also of considerable importance. These factors are usually outside the control of the surgeon. The surgeon, however, can choose the technique of closure and the suture material. [3]

The technique of closure should be quick, easy, cost effective and simple, while maximising wound cosmesis and patient satisfaction. The technique should be based on evidence and not only on the surgeon's preference and tradition. Any of the methods used should be able to restore the physical integrity and function of the injured tissue. Appropriate and careful selection of suture material is

important. Choosing the appropriate materials and adhering to good wound closure technique will ensure optimal wound healing [4] . The ultimate goal of any skin closure technique is to produce skin approximation and adequate healing with minimum wound complications like pain, infection, scarring and keloid formation. Most important to the patient is the pleasing aesthetic affect. Cost of the procedure should also be considered. Closure should serve both functional and aesthetic purposes [5]. Effective wound closure includes elimination of the dead space by approximating the subcutaneous tissues, minimization of the scar formation by careful epidermal alignment, and avoidance of a depressed scar by precise approximation of the skin edges. Atraumatic handling of the wound combined with avoidance of tight closures and undue tension contribute to excellent results. The wound should be able to withstand the daily tensile forces and be able to heal expeditiously and effectively when it is most vulnerable.

LITRATURE REVIEW

One of the lasting reminders of any abdominal surgery, and most noticeable to the patient, is the scar made by the incision. The gynaecologist must be very cautious to take into consideration the underlying pathology, suspicion of malignancy and the underlying comorbid state of the patient. Despite increasing emphasis on evidence based medicine, there are very little reliable data

available about the best method of wound closure. The methods of skin closure vary widely and are largely the surgeon's personal choice.

Frishman et al [6] in his study of 50 patients randomized 25 patients in each group (staples vs. subcuticular sutures) to assess the pain and cosmesis at discharge and six weeks post operatively. He found that there was less post operative pain if wound was closed by subcuticular sutures when compared to staples ($P = 0.01$) at the time of discharge and at the post operative visit ($P = 0.002$). Also incisions closed with subcuticular suture were found to be more cosmetically appealing to both patients ($P = 0.04$) and their surgeon ($P = 0.01$) at the postoperative visit. According to this study less time was required for approximation of the incision by staples than by subcuticular sutures (47 ± 4 seconds vs. 605 ± 33 seconds). In a trial of skin closure after laparotomy for gynaecological surgery where 90 patients were randomised, Obermair [7] randomised patients into three groups (Staples, Caprosyn, and monocryl). He suggested that the wound closure methods have similar short term pain and cosmetic outcomes, as well as rate of wound complications. The decision of the most appropriate closure method was left to individual surgeons. Gaertner et al. [8] conducted a study by randomizing 100 patients undergoing caesarean section. All patients had a Pfannensteil incision and were randomized to staple closure ($n=51$) and compared to subcuticular sutures ($n=49$). Wound cosmesis was assessed by the patient and non-blinded

physician. They found that both the methods have comparable cosmetic outcome when the scar is evaluated for colour, consistency, adhesion, keloid formation, cross hatching, separation of edges and consistency of the underlying tissues. However they found that placement of the subcuticular suture lengthened the average surgical time by 3.3 min ($P < 0.05$). In a systematic review by the Cochrane Database [9] it was found that there is a clear lack of data on materials and techniques of skin closure. In addition to this the existing data of skin closure studies have been limited by small numbers and poor study design.

An advantage of surgical clips (also called staples) includes rapid speed of closure. However, there are conflicting results regarding rate of infection, evaluation of cosmesis and postoperative pain. In a randomised trial done by Juline-Anne Rousseau and her colleagues in 2009 [10] it was found that pain at six weeks was significantly less in the staple group when they compared the two methods of skin closure during caesarean sections. This study was done by randomising 101 patients where 52 had their incision closed by subcuticular suture and for the other 49 patients staples were used. In her study operating was shorter for the staple group as in all the other studies (24.6 vs. 32.9 minutes; $P < 0.0001$). They also found no difference in the appearance of scars and satisfaction of the women. In a review done by Altman et al [11]

the relationship between different closure techniques and wound infection and cosmesis was found not to be clear.

In the trial done by Antonella Cromi [12] , 180 women undergoing caesarean section were randomised to either subcuticular suture or staple group. Their conclusion was that stapled wounds and those closed with subcuticular sutures result in equivalent cosmetic appearance. They evaluated the patients at 2 months and at six months postoperative. A recent study done by Basha et al [13] 435 patients were randomised to evaluate the rate of wound complications using the two different methods of wound closure staples (n=197) vs. subcuticular (n=219). The study concluded that staples were associated with a four-fold increased risk of wound separation (OR 4.66; 95% CI [2.07-10.52], $P < 0.001$). In addition, there was 5-fold decrease in patient satisfaction. In her study the staples were removed on the third or fourth post operative day in contrast to all the other studies where staples were removed on the seventh post operative day. It is possible that the staples were removed too early. Disadvantages included the need for a second operator to evert and re-approximate skin edges during staple placement, a greater risk of crosshatch marking, and less precise wound approximation in the staple group. The cost of surgical staples is usually more than that of suture material. Also there is a need for patient follow up for removal of staples [14]. Clay et al [15] in their meta-analysis of trials comparing staples and subcuticular sutures found that wound separation and wound

complications rates were higher with staples. The use of staples reduced the operating time (weighted mean difference, -5.05 minutes; $P = 0.021$). It also showed that data on the postoperative pain and patient satisfaction is still insufficient for the analysis and more research is needed in this field. Several studies were done in general surgery but with inconclusive results. [16-19] Similar results were found for studies done on animals. [20-24]

ANATOMY OF THE ANTERIOR ABDOMINAL WALL

It is of paramount importance for the surgeon to have detailed knowledge of the anatomy of the anterior abdominal wall and the suspected pathology in order to make the correct choice about the location of the incision. Thorough knowledge is also essential to avoid injury to the vessels and nerves and to close any incision with minimum chance of wound dehiscence and herniation.

The abdominal organs are protected by the anterior abdominal wall. The upper part of the abdominal wall lies in the abdomen and the lower part in the pelvis. Cephalad, the abdominal wall extends from the xiphisternum and the costal cartilage of the 7th to 10th rib. Caudally it extends to the iliac crests, anterior superior iliac spines, the inguinal ligaments, pubic tubercle, the pubic crest and pubic symphysis [25]. Anteriorly and laterally, the walls are made up of relatively thin expansible muscular sheet. Posteriorly there is thick layer of back muscles and the vertebral column.

The integuments of the anterior abdominal wall consist of overlying skin, fascia, subcutaneous tissue and muscles with aponeurosis. These structures are attached to the bony pelvis. The transversalis fascia, peritoneal fat and peritoneum are attached to the inside surface. Nerves and blood vessels are present throughout the anterior abdominal wall.

FUNCTION

The muscles of anterior abdominal wall assist with respiration and certain expulsive efforts like in urination, defecation, coughing and parturition. They work in conjunction with the muscles of the posterior abdominal wall in rotational movements at the waist and extension movements at the hips. Their tone plays a major role in the protection of the viscera of the abdominal cavity.

CONTOUR

The shape of the abdomen significantly depends on the lifestyle, BMI, intra-abdominal pathology, parity and posture at every age and in both genders. The muscle mass and previous pregnancies can result in variation in the contour and may present problems in correct choice and placement of incisions [26].

SKIN

It is worthwhile to examine the skin as it can influence the selection of the incision. Important points to note are the previous operation scar, any pigmentation or herniation or any bulging due to intra-abdominal pathology.

In 1861, Langer described the cleavage lines of skin that pull the skin edges apart when cut across[27] . These are named after him as Langer lines. According to him the bundles of collagen fibres in the dermis run in parallel lines. These lines run horizontally across the abdomen. A vertical incision in the skin of the abdomen cuts perpendicular while a transverse incision cut parallel to these lines. Thus transverse incisions heal with a relatively little scarring and relatively a greater force is needed to disrupt a surgically repaired incision. In contrast vertical incisions will result with a broad scar, especially in the lower abdomen.

The skin is supplied by seventh to tenth intercostal nerves and the first lumbar nerve in the form of the iliohypogastric nerve.

UMBILICUS

A prominent feature of the anterior abdominal wall is the umbilicus. In a well-conditioned patient the umbilicus is midway between the xiphisternum and the pubic symphysis and lies at the level of approximately the 3rd or the fourth lumbar vertebrae [28]. In a multiparous patient or obese patient it can be displaced. This can also be true in a patient with abdominal pathology.

At the umbilicus the skin of the abdomen is loosely attached to the superficial fascia. The umbilicus contains the obliterated umbilical arteries and the umbilical vein that were in the umbilical cord of the fetus.

SUPERFICIAL FASCIA

The superficial fascia serves as a major site for the deposition of fat in obese individuals. There are two patterns of distribution. Above the umbilicus, the subcutaneous fascia and fat cells are in a single layer of tissue. Below the umbilicus, it is divided into two layers. The superficial layer is called camper's fascia (fatty layer) and the deep layer is called scarpa's fascia (membranous layer) [29]. Scarpa's fascia serves as a firm unit for suturing the subcutaneous fascia in repairs after abdominal surgery. It is continuous with the superficial perineal fascia of the perineum, also with the fascia lata of the thigh inferior to the inguinal ligament.

ABDOMINAL WALL MUSCLES

The muscles of the anterior abdominal wall is mainly composed of four paired muscles namely rectus abdominus, internal and external oblique and the transversus abdominus.

Rectus abdominis: It is long strap like muscle that runs from the rib cage to the pubic bone. It forms the vertical component of the anterior abdominal wall. The paired muscle lie on the either side of the linea alba. The muscles are broad superiorly and narrow inferiorly. They are attached to the fifth, sixth and seventh costal cartilage above and to the pubic symphysis below.

External oblique: This broad and thin muscle arises from the outer surfaces of the lower eight ribs. Its fibres fan out and are inserted medially into the xiphoid

process, anterior portion of the iliac crest and the linea alba. On its medial side it fuses with its fellow of the other side while inferiorly it forms the inguinal ligament that extends from the anterior superior iliac spine to the pubic tubercle. It has a posterior free border [30] .

Internal oblique: This is also a broad and thin muscle that arises from the thoraco-lumbar fascia, the anterior two thirds of the iliac crest and the lateral two thirds of the inguinal ligament. It lies deep to the external oblique muscle. From its origin its fibres fans out to be inserted to lower border of the three ribs and their costal cartilages. The intermediate fibres become aponeurotic and forms the rectus sheath before it joins with its fellow on the other side at the linea alba. The lower fibres form a tendon and join with the transverses abdominus tendon to form the conjoint tendon that is inserted at the symphysis pubis.

Transversus abdominis: This is the deepest muscle. It arises from the inner surfaces of the lower six cartilages at the tips of the transverse processes of the lumbar vertebrae, the inner lip of the iliac crest and the lateral half of the inguinal ligament. Its fibres run medially and become aponeurotic and form the rectus sheath. Then these fibres join its fellow on the opposite side at the linea alba. The lowermost fibres are attached to the pectineal line by the conjoint tendon.

Pyramidalis: This triangular muscle located at the lower end of the anterior abdominal wall. It arises from the superior pubic ramus and the pubic tubercle and inserts into the linea alba [31].

LINEA ALBA

The linea alba stretches from the xiphoid process to the pubic symphysis. It is formed by the fusion of three muscles namely the internal oblique, external oblique and the transverses abdominus. Its widest margin is 3cm superior to the umbilicus and has varying distances depending upon the point of reference along the anterior abdominal wall [32]. The anterior wall of the rectus sheath is firmly attached to the rectus muscle while the posterior wall is not attached to the muscle

RECTUS SHEATH

The rectus sheath is a long fibrous sheath that encloses the rectus abdominus muscle and the pyramidalis muscle. It also contains the anterior rami of the lower six thoracic nerves and the superior and the inferior epigastric vessels and the lymph vessels. It is formed by the aponeurosis of the three lateral abdominal muscles i.e. internal oblique, external oblique and the tranversus abdominis.

It is very important to consider this sheath at three levels:

Above the costal margin, it is formed by the external oblique anteriorly and by the thoracic walls posteriorly i.e. the fifth sixth and seventh costal cartilages and the intercostals spaces.

Between the costal margin and the level of the anterior superior iliac spine, the aponeurosis of the external oblique is directed in front of the muscle and the aponeurosis of the transverses oblique is directed behind the muscle while the aponeurosis of the internal oblique splits to enclose the rectus muscle

Between the level of the anterior superior iliac spine and the pubic symphysis, the aponeurosis of all three muscles forms the anterior abdominal wall. Here the posterior wall is absent and the muscle lies directly on the fascia.

The aponeurosis forming the posterior wall pass in front of the rectus at the level of the anterior superior iliac spine, the posterior wall has a curved free border called the arcuate line. At this point the inferior epigastric vessels enter the rectus sheath to anastomose with the superior epigastric vessels. The arcuate line is absent in as many as 30 percent of individuals [33].

VASCULATURE

The anterior abdominal wall is supplied by the superior and the inferior epigastric arteries, the deep circumflex iliac arteries, the posterior intercostal arteries and the four lumbar arteries.

The superior epigastric artery is a branch of the internal thoracic artery. It supplies the upper central part of the anterior abdominal wall and anastomoses with the inferior epigastric artery [34].

The inferior epigastric artery is a branch of the external iliac artery. It supplies the lower middle part of the anterior abdominal wall and anastomoses with the inferior epigastric artery [34] .

The deep circumflex iliac artery is branch of the external iliac artery. It supplies the lower lateral part of the anterior abdominal wall.

The lower two posterior intercostal arteries are branches of the descending thoracic aorta and supply the lateral abdominal wall.

The four intercostal arteries are branches of the abdominal aorta and also supply the lateral abdominal wall.

NERVES

The anterior abdominal wall is supplied by the anterior rami of the lower six thoracic and the first lumbar nerves.

LYMPHATICS

The lymph drainage of the anterior abdominal wall can be divided into superficial and deep. The superficial lymph vessels above the level of the umbilicus drain anteriorly into the anterior axillary lymph nodes and those below the umbilicus drain into the deep inguinal lymph nodes. The deep lymphatics drain along the arteries into the internal thoracic, external iliac, posterior mediastinal and the para-aortic nodes [28] .

PHYSIOLOGY OF SKIN

The skin is one of the largest organs of the body. It has many important functions like prevention of bacterial infection and it also protects against mechanical injury and from the harmful effects of ultraviolet radiation.

WOUND HEALING

The process of wound healing begins soon after the closure of the wound. It heals by first intention as only focal disruption of the epithelial basement membrane takes place and relatively few epithelial cells and connective tissue cells die while incising the skin. Moreover surgical wound closure directly opposes the tissue layers, which serves to minimise new tissue formation within the wound. Epithelial regeneration predominates by fibrosis.

The healing of the surgical incision takes place in three essential steps.

1. Inflammation, where haemostasis is achieved and mobilization of the immune system take place.
2. Tissue formation by angiogenesis and fibroblast proliferation and migration.
3. Matrix formation and remodelling by laying down of fibronectin, hyaluronic acid, proteoglycans and type III collagen that is replaced later by type I collagen [35] .

After the closure of the wound the narrow incision space immediately fills with fibrin and clotted blood. The small cutaneous vessels undergo spasm. The

neutrophils start migrating towards the clot and platelet aggregation also takes place. The neutrophils and macrophages release proteolytic enzymes that help in the breakdown of damaged tissue.

Epithelialization occurs in the epidermis within 24 hours. The epithelial cells from both edges show increased mitotic activity. These migrate and proliferate along the dermis depositing basement membrane components. The cells meet in the midline beneath the surface scab, yielding a thin but continuous epithelial layer. Dehydration at the surface produces a scab to cover and protect the healing repair site. Complete bridging of the wound occurs within 48 hours of suturing.

After 48 hours neutrophils have been largely replaced by macrophages and minimal granulation tissue fill the incision space. Collagen fibres appear at the incision margin but still do not completely fill the incision. Epidermal cells proliferate and thicken.

Neovascularisation then takes place and reaches its peak at day 4 as granulation tissue fills the incision space. Collagen fibrils become abundant and start bridging the incision. The epidermis thickens more and keratinisation of wound takes place. Wound contraction also takes place at this point.

In the second week there is continued collagen accumulation and fibroblast proliferation, however leukocyte infiltration decreases. Oedema subsides and

vascularity is reduced. The scar starts to blanch as there is regression of the vascular channels and increase in the deposition of the collagen.

After the first month the scar is composed of connective tissue that is covered by normal epidermis. The dermal appendages that are destroyed in the line of the incision are permanently lost. Collagen production and remodelling continue for up to twelve months.

WOUND STRENGTH

Wound strength is usually about 10% at the end of one week. It accelerates after that in the next few weeks. It is 20% by the 3rd week and 50% by 4th week. If the wound is sutured carefully, it should regain its maximum strength of 70%-80% of the normal skin when it is fully healed in 3-6 months time [36]. This process usually takes three to four months [37]. The strength of the wound depends on the placement of the suture and extent of the incision and absence of any factors that may interfere with wound healing.

SURGICAL WOUND CLOSURE

HISTORY

The history of surgical sutures is more than 2000 years old. It is not clear when mankind learned to use strings or animal parts to ligate bleeding vessels or approximate tissues. Any material that was used to re-approximate tissues is commonly referred to as suture and the act of re-approximating of tissues is called suturing. Plastic surgeons like Susruta (ADc380-c450) used flax, hemp

and hair to suture the wounds. At that time the jaws of the black ant were used as surgical clips in bowel surgery. Over the centuries different materials were used that were derived from a variety of sources like metals (gold, silver, and tantalum), plant material (linen and cotton) and animal products (horse hair, silk, intestinal tissue and tendons). In 30 AD, the Romans described the use of suture and staples, and the use of silk and catgut in 150 [AD]. Before the end of first millennium, Avicenna described monofilament the use of pig bristles for

Suturing wounds [38]. J. Marion Sims [39] (1813-1883) also called the father of gynaecology was the first person to find the surgical cure for fistulas His technique using silver-wire sutures led to successful repair of a fistula, and this was reported in 1852. Surgical and suture techniques evolved further in the 1800s with the development of sterilization procedures. Finally, modern methods of manufacturing and classification of sutures (using United States Pharmacopeia) created uniformly sized sutures.

Catgut and silk are the natural materials that were the mainstay of suturing products, and they remain in use even today. Catgut is the oldest suture that is derived from the sheep intestine. Actually the name derived from “kit gut” which referred to the strings of the musical instruments known as the kit. Over the years the term has evolved into catgut [37] .

The first synthetics were developed in the 1950’s and further advancements have led to the creation of different forms used today

MATERIALS USED FOR SKIN CLOSURE

Choice of materials used is very important for adequate healing and aesthetically pleasing affect. Different materials used are surgical clips, sutures, adhesive glue, and tapes. There is also on-going research in welding of the wound by laser energy.

STAPLES

Staples, also called clips, are made of high quality stainless steel. They are available in regular and wide sizes. It consists of the cross – member, legs and the tips.

The cross member lies on the surface of the wound perpendicular to the skin. The legs are vertically placed in the skin and the tips secure the staple parallel to the cross member[d].

The staples are disposable and applied by stapler. There are usually 5-35 staples loaded in the stapler. The stapler is disposable and easy to use as they have handles to grip and control[g]. Most regular staples are 4-6mm wide and 3.5-4mm high. Wide staples used for thicker skin are 6.5-7.5mm wide and 4-5mm high.

Staples are less reactive than other traditional suturing materials. Staples can be applied by minimal skin penetration and few organisms are carried to the lower skin layers. They are removed painlessly by using a specialized set of

extractors. The disadvantage of using staple is that the patient has to go back in seven days for its removal and they are expensive.

SUTURES

A surgical suture is any material used to approximate the wound edges. Suture choice should be based on the type and site of the incision, the condition of the patient and the characteristics of the suture material. In general the ideal suture should be non-allergenic, resistant to infection and absorb at a predictable rate. It should pass easily through the tissues. An ideal suture should have knot security, adequate tensile strength, plasticity and elasticity. Last but not the least suture it should be cost effective [e].

SUTURE CHARACTERISTICS

The physical characteristics of sutures greatly influence its utility; these characteristics include configuration, size, tensile and knot strength, diameter, elasticity, plasticity and memory.

Configuration: The configuration of the suture is based on the number of strands of the material used to fabricate it.

Size: Sutures are available in different sizes. Modern sutures are classified for size from number 5 (with the thickest diameter) to number 11-0 (with the smallest diameter). Progressively smaller sizes are expressed with increasing number of zeros such as 4-0, 5-0 and 6-0. Number 2 suture material is the

thickest available at the moment. From number 1 to 5-0 the sutures are usually used for macro surgery and from 6-0 to 10-0 sutures are used for microsurgery.

Tensile Strength: The tensile strength is the amount of weight required to break the suture divided by its cross-sectional area. Implantation and tying of the suture decreases its tensile strength. In selecting the suture material, the tensile strength of a suture should not need to exceed that of the tissue it is securing.

Knot pull strength: All suture patterns start with one basic component -the square knot [40] . It is the weakest portion of the suture. Knots must be tied adequately as the extra throws do not increase the strength of the knot but do add to the bulk of the knot. This can result in tissue reaction especially if the knot is buried in the tissues.

Elasticity: It is the ability of the suture material to retain its original form and length after stretching. After swelling of the wound subsides a good suture will retain its elasticity and keep the wound well approximated.

Plasticity: It is the ability of the suture to retain its new form and length after stretching. Plasticity is good as it allows wound swelling, thereby decreasing the risk of strangulated tissue and crosshatch marks.

Memory: It is related to the elasticity and plasticity. It is the inherent ability of the suture to maintain its shape after its tying off the knots. A suture with high memory is stiff and thus an extra throw may be needed to prevent loosening.

Prolene is a good example of the suture with high level of memory.

Pliability: It is the ease with which a suture can bend. Multifilament suture are usually easy to tie as they can bend easily.

Coefficient of friction: The coefficient of friction is the ease with a suture passes through the tissues e.g. multifilament suture causes more tissue injury when they are passed through the tissues as they have high coefficient of friction.

Tissue Reaction: Various sutures cause different degrees of tissue reactions that can interfere with wound healing. The amount of material is also important, especially with respect of the knot volume. Allergic reaction can be caused by different suture materials but it is very rare.

Sutures are broadly classified as absorbable non-absorbable, monofilament or multifilament (braided and twisted), natural and synthetic.

They are available in different sizes ranging between 8 to 27 inch lengths.

ABSORBABLE SUTURES

Absorbable sutures are defined as those sutures that lose their maximum tensile strength in sixty days[i]. They are digested by body enzymes.

Examples of the absorbable sutures are plain, chromic, and fast absorbing catgut.

Cat gut is a natural product derived from the collagen of sheep or cattle [37] . It was the first absorbable suture material. As plain catgut is made of foreign protein, it causes marked inflammatory response to the tissues. It is packed in alcohol to prevent it from drying. Plain catgut retains tensile strength for only five to seven days. However, it is only completely absorbed by 70 days. Chromic gut is treated with chromic salts to resist body enzymes and thus slows absorption and tissue reactivity. They retain their tensile strength for 10 to 14 days. Chromic gut is thus useful in suturing in the oral cavity. It may also be used for ligation of blood vessels. Fast absorbing gut is a new material that is treated with heat to accelerate the tensile strength loss and absorption. It is used for epidermal suturing like facial lacerations. It is reasonable to reinforce these sutures with tapes. It can also be used for securing both split and full thickness skin grafts. They have few disadvantages like more fibrosis and thus an ugly scar.

Absorbable sutures are not suitable for the closure of the abdominal wounds as it increases the risk of an incisional hernia although it can often be used to ligate vascular pedicles. It is ideal for Pomeroy tubal ligation as it dissolves rapidly and thus allows the severed ends to fall apart.

Other examples of absorbable sutures include polyglycolic acid (Dexon), polyglactin 910 (Vicryl), polydioxanone (PDS), polytrimethylene carbonate and poliglecaprone.

POLYGLACTIN 910 (VICRYL)

It was added to the surgeon's armamentarium in 1974. It is coated with polygalctin 370, which facilitates knot tying and reduces tissue drag. It is a lubricated, braided synthetic material with excellent handling and smooth tie down properties. It maintains 55% of tensile strength at 14 days. Complete absorption occurs in 60 to 90 days. However, it requires extra throws for knot security. It is available as a clear or a violet suture. It causes less tissue reaction than catgut as it undergoes hydrolysis instead of enzymatic breakdown. It reabsorbs at a constant rate.

Two other polyglactin sutures were developed by Ethicon, Vicryl Rapide and coated Vicryl. Vicryl rapid is ionised with gamma rays to speed its absorption. It is completely absorbed in 35 days. This makes it useful as a buried suture in a wound requiring limited dermal support. The other newest antibacterial suture is Coated Vicryl Plus Antibacterial. Triclosan is used to coat the suture, which is nontoxic and not irritant [a]. It inhibits bacterial colonization of the both *staphylococcus aureus* and *staphylococcus epidermidis*. Thus this suture is more useful in wounds that are at increased risk of infection.

POLYGLYCOLIC ACID (DEXON)

It is a synthetic absorbable braided suture. It has properties similar to Vicryl. This suture is coated but its coating is partly removed when gliding through the tissues. Thus it is a little difficult when it comes to tying of the knots.

POLYDIAXANONE (PDS)

PDS is a synthetic monofilament delayed absorbable suture. It retains 90% of its tensile strength by 14 postoperative days and retains 50% of the tensile strength by day 30. It is reabsorbed over a period of 180-210 days. When wound healing is expected to take a longer time, these sutures should be considered. Because it has only a single filament it causes less tissue reaction. It is also a little more expensive.

POLYTIMETHYLENE CARBONATE (MEXON)

It is a synthetic monofilament. It has the same qualities as Dexon. The majority of its tensile strength is still present at five to six weeks. It has excellent knot security especially when six square knots are used. The only disadvantage is that it is a little more expensive.

NONABSORBABLE SUTURES

These are defined as suture material that maintains its tensile strength for more than 60 days.

They can be monofilament like polypropylene, stainless steel wire or nylon. Or it can be braided like silk or cotton.

Polypropylene is a synthetic monofilament suture. It is used in infertility operations and also used for suturing of anterior rectus sheath after longitudinal incisions. It causes less inflammation when compared to the other multifilament sutures in this group. Polypropylene (Prolene) is a good example of a suture with a high level of memory [h].

Wires are not popular as it can cut the surgeons gloves. It is also difficult to tie and breaks easily if bent sharply. If it is placed too closely to the incision edge it can cut through the tissues.

Nylon is a monofilament suture usually used for permanent closure. However it sometimes breaks up in the tissues after a while.

Silk and cotton loses its tensile strength in years' time. It should never be used in gynaecological surgery as it causes severe fibrosis and it acts as a nidus of infection.

NEEDLES

Needles are necessary to carry the suture material through the tissues. The choice of the needle depends on the type of the tissue, its location and accessibility. It also depends on the surgeon's choice. The needle consist of three parts namely eye, body and the point.

Eye: The eye is the end of the needle attached to the suture. It can be traumatic (if the suture material has to be passed through it) or atraumatic (when the suture is attached to the suture). Traumatic needles are seldom used in gynaecological practice as they cause trauma as they are passed through the

tissues. One example is the Mayo needle. There are also difficulties with threading and the need to pull a double suture through the tissues.

Body: The body of the needle is the portion between the eye and the point. It is grasped by the needle holder while suturing. It determines the shape of the needle and can be of different sizes and shapes. Curved needles are used for cutaneous suturing. The curvature may be $1/4$, $3/8$, $1/2$, $5/8$. The most commonly used curvature used is $3/8$ and $1/2$ that require minimal pronation of the wrist for large and superficial wounds. The $5/8$ curvature is used for suturing in confined places like the oral cavity.

The shape of the body is also very important. Usually it comes in three shapes: round, conventional cutting, and reverse cutting.

A round needle is tapered and has no cutting edges. So it passes through tissues by stretching it. This is used for suturing soft and elastic tissues like vascular pedicles, peritoneum and the subcutaneous fat. On the other hand cutting and reverse cutting needles are used for skin. They pass through the tissues by cutting the path. These have triangular shapes and a tendency to cut through the tissues[f]. They must never be used for ligating vascular pedicles, since a blood vessel can easily be injured by the cutting edge of the needle. A new quad-sided needle with diamond geometry is also available. It is designed to minimise tissue trauma.

Point: The point of the needle extends from extreme tip to the maximum cross section of the body. It can be cutting, conventional cutting or reverse cutting. It is also available with a rounded blunt tip at the end of the tapered shaft. This is used for suturing friable tissues. This blunt tip needle is advocated by surgeons for suturing other tissues too as it has the advantage of reduced likelihood of penetrating through the surgeon's gloves or the skin. Cutting needlepoints are useful for the skin and round points for soft tissues and fascia.

ADHESIVE GLUE

Use of adhesives can simplify skin closure and alleviate the problems inherent to sutures. Problems like reactivity and premature absorption can occur with sutures and can lead to an undesirable result, both functionally and cosmetically.

There are two types of tissue adhesives. Octylcyanoacrylates and N-butyl-2-cyanoacrylate. They are quick and easy to apply and provide protection against microbes and provide a water tight coating. They require the wound to be completely approximated before application [b]. Also if the adhesive seep into the wound bed then it impairs wound healing by inducing inflammatory reaction. Adhesives will stiffen when dry. Bathing is not contraindicated but prolonged soaking should be avoided. In the setting of tension-free inguinal hernia wounds, NBCA is comparable to traditional suture closure[c].

They are more suitable for the areas that are not mobile. Allergic reactions are very rare, but may include inflammation and swelling.

TAPES

Tapes can be used for the closure of small wounds or as an adjunct to other methods of wound closure. Advantage of tapes include that it is quick and easy and also does not leave hatch marks and the patient does not have to follow up.

The disadvantage is that the wound edges cannot be fully everted. Moisture, soap and dampness that collects under it can delay wound healing. They are available in different shapes and colours.

INCISIONS

DEFINITION

It is the cut or wound made into the body tissues or organ especially during surgery. The scar is the result of such a cut.

TYPES

There are many types of incisions for gynaecological surgery and selection of any incision must be highly individualized. Although cosmesis is a very important aspect of the incision, the selection of the incision should not be dictated by the patient if it may compromise the surgical approach. On the other hand unduly enlarged or poorly positioned incisions may increase the risk of herniation, infection and dehiscence in addition to the unsightly cosmesis [m].

In general, abdominal incisions for most gynaecological procedures can be divided into transverse or vertical incisions. Very rarely oblique incisions are used.

TRANSVERSE INCISION

Transverse incisions generally have an aesthetically pleasing effect as they are parallel to the Langer lines. They are relatively less painful and do not interfere with respiration postoperatively. They are strong and there is less chance of wound dehiscence. The disadvantage of the incision is that it is almost impossible to explore the upper abdomen. So it cannot be used in patients with suspected gynaecologic malignancies. It should not be used when more pelvic exposure is needed as in severe endometriosis or large fibroids with distortion of the lower uterine segments. Transverse incisions are also not advisable to be used for laparotomies for large abdominal masses. It is technically a difficult incision and more time consuming. It is also relatively more haemorrhagic and there is more chance of haematoma formation. When wide transverse incisions are made the iliohypogastric and the ilioinguinal nerves can be damaged. Both of these nerves are sensory in function. Injury to the former can result in sensation changes over the mons pubis, whereas injury to the latter results in sensation changes over the labia majora. A widely placed transverse incision can result in numbness over the upper part of the anterior thigh. Occasionally if the nerves are damaged at the level of the anterior superior iliac spine it can

weaken the lower fibres of the internal oblique and the transversus abdominis predisposing the patient to an inguinal hernia.

The common transverse incisions are as follows: (They are usually named after the surgeons who first described them.)

A Pfannenstiel incision: It is a slightly curved (concavity upwards) transverse incision following the lines of Langer approximately 3 cm above the pubic symphysis. It is very important to make this incision symmetrically so that it has the same length on both sides of the midline. Usually it is 10 to 15 cm long and extends from the skin and the subcutaneous fat to the level of the rectus sheath. Then the anterior sheath is transversely incised with a knife on either side of the linea alba, where after it is cut open further with scissors. The anterior rectus sheath is dissected from the rectus muscles (superior and inferior) by inserting the fingers on either side of the cut edge of the sheath. The rectus muscles are separated from each other and peritoneum opened vertically [n].

Joel Cohen incision: It is a modified Pfannenstiel incision. The main difference is that after the skin incision, the sharp dissection is limited to the medial aspect of the incision. In case of repeated laparotomies this incision cannot be used because of the risk of increased fibrosis. The advantage of this incision is that there is less blood loss and it is much quicker

A Maylard incision: It is similar to the Pfannenstiel incision except that in this incision the rectus muscle is completely or partially incised transversely. It not

routinely used except when in difficulty, when a larger exposure is needed during Pfannenstiel incision e.g. when a large ovarian tumour has to be removed or when a large baby has to be delivered. The Pfannenstiel incision and the Maylard incision have been compared directly from caesarean delivery and were judged to be comparable in this situation [41]. Sometime it is used for radical hysterectomy with pelvic lymph node dissection. It can also be used for cosmetic purposes in case of laparotomy for suspicious adnexal mass in young patients. In that case patient must be informed that if malignancy is found it has to be converted to a J- shaped incision.

It is very important to note that the inferior epigastric arteries run on the posterior lateral border of each rectus muscle. It is advisable to tie these arteries before the dissection of the muscle to avoid tearing of the vessels, vessel retraction and haematoma formation [j] [k].

A Cherney incision: This incision resembles the Maylard incision except that the rectus muscle is freed from its tendinous insertion at the pubic symphysis. The rectus muscles are then retracted cephalad to improve exposure. This incision gives an adequate exposure for the space of Retzius so it very useful for urinary incontinence procedures. When closing this incision the rectus muscle has to be stitched back at its tendinous insertions with insoluble or delayed soluble sutures [L].

Kuster incision: A low transverse incision which is a slightly curved transverse incision below the anterior superior iliac spine and extends below the pubic hair line, through subcutaneous fat down to the aponeurosis of the external oblique and the anterior sheath of the recti. It can be used for total abdominal hysterectomy[n]. It is a cosmetically better incision as it is lower.

Moreover it is stronger as the incision through the skin and that through the rectus sheath are made in different places. However this incision should not be used for caesarean sections as it allows less space for the delivery of the baby.

VERTICAL INCISIONS

Vertical incisions were the only incisions used earlier because it was easy and access to the abdominal cavity was quick and adequate. There was a fear that transection of the rectus muscle will leave a defect in the abdominal wall due to its retraction. With time it was found that adherence of the recti to the anterior rectus fascia prevents this retraction. Vertical incisions can be extended upwards easily. This is very useful if a large tumour is to be removed or where exploration of the upper abdomen has to be done. This may also be of benefit operations for ovarian cancer where it is important to explore the liver and the diaphragm and to take samples for cytological examinations.

Randomized trials have shown that midline incisions have similar rates of dehiscence when compared with transverse incisions [42, 43].

Usually one of the two vertical incisions is used .A subumbilical midline incision or the left paramedian incision

The subumbilical midline incision: This incision is used if the surgeon feels that there might be difficult surgery or incision has to be extended as in case of ovarian tumours where the liver or the inferior surface of the diaphragm has to be explored. It is also the preferred incision in case of a suspected intra-abdominal haemorrhage e.g. in a shocked patient with ectopic pregnancy. The other indication may be large size of a tumour. Patients must always be counselled about the incision before the surgery. If this incision has to be extended upwards it has to be curved around the umbilicus that can result in an ugly scar [n].

A left paramedian incision: It is same as the above incision except that in this incision the rectus sheath is dissected from the muscle. The advantage of this incision is that it can be easily extended to the upper abdomen and there is a little risk of herniation. The paramedian incision may decrease the risk of hernia or dehiscence as compared to midline incision, however conflicting data has been reported [30, 44].

OBLIQUE INCISIONS

The most common oblique incisions are as follows:

A Mcburney incision: This is an incision used for appendectomy. This incision is perpendicular to the imaginary line drawn from the umbilicus to the anterior

superior spine at the McBurney's point. It is easily expanded and the cosmesis is excellent [45]. It is used when the diagnosis is certain otherwise a left paramedian should be used.

A Rutherford Morrison incision: This incision is also used for appendectomy if the appendix is situated behind the caecum. It is an oblique muscle splitting incision which extends supero-laterally from the McBurney point

WOUND COMPLICATIONS

Wound complications can cause significant morbidity following operations. The risk for complications depends on the indication of the operation and the surgical technique combined with the comorbid problems of the patient. Risk factors for wound complications include diabetes, cardiovascular disease, cancer, immune-suppression, obesity [36, 46], smoking, previous surgery and length of incision [38], malnutrition and prior radiation. Surgical wounds heal through an orderly sequence of physiological events. Mechanical failure or failure of wound healing can lead to wound complications. Wound complications can arise immediately or can be delayed. Important early complications to recognise are the wound hematoma, seroma, wound dehiscence or hernias besides infection and nerve injury.

HEMATOMA

A hematoma is defined as a collection of blood in the wound at the incision site. It is the result of inadequate haemostasis. Likewise a seroma is the collection of

serum. Small haematomas can be managed conservatively while the large haematomas have to be drained to avoid the complication of infection and the incision to separate. In the absence of infection the wound can be closed immediately. Otherwise, the opened wound should be packed until granulation tissue is formed and the wound can be closed at a later stage by secondary suturing. It can be prevented by meticulous haemostasis techniques.

INFECTION

Infection occurs in approximately 5% of uncontaminated surgical wounds [n]. The severity of the infection determines the procedure to be followed and the need for antibiotics. Infected wounds are opened, explored, drained, irrigated, debrided and at times dressed open. Once the infection is cleared and granulation tissue is formed then the wound can be closed secondarily. Appropriate dressing of the wound is of paramount importance. Prophylactic antibiotics are used to reduce the risk of infection. Also antibiotics should be used if the patient develops systemic clinical manifestations. Infection can be prevented by the use of appropriate antibiotics and appropriate wound closure techniques. Surgeons can also modify the rates of infection by proper skin preparation, maintenance of sterile conditions, gentle handling of the tissues and avoiding tissue ischemia.

FASCIAL DISRUPTION

Fascial disruption is defined as the separation of wound edges with or without protrusion of the abdominal contents. It occurs when the abdominal wall tension overcomes tissue or suture strength, or knot security. It is more common in midline incisions than transverse incisions. The incidence of wound dehiscence is 0.1%-0.7%. This low incidence in gynaecological practice is due to the lower infection rate, healthier patients and lower rate of bowel enterotomies.

Fascial disruption may be early or late. Early facial disruption is a medical emergency with significant morbidity. Late facial disruption can lead to an incisional hernia. It can be prevented by employing the proper methods of wound closure e.g. by placing the suture less than 1cm from the wound edge and avoiding tissue necrosis by excessive pulling on the suture. The choice of correct suture material and the knot security is also very important. Late complications include nerve injury, hernia and keloid formation

Nerve injury can result from transection, entrapment of nerves and compression/stretching (from retraction of tissues or positioning of the patient). It can cause distressing symptoms of pain, loss of sensation and abdominal wall weakness predisposing to a hernia.

Significant predictors of chronic pain following Caesarean section include numbness after the primary incision, repeat Pfannenstiel incision and an emergency procedure [47].

CLINICAL STUDY: SKIN CLOSURE TECHNIQUE

This is a study to determine the patient satisfaction comparing two techniques of skin closure in gynaecological procedures; subcutaneous closure versus closure by staples.

NULL HYPOTHESIS

Subcutaneous wound closure is better than closure by staples with regards to patient satisfaction in terms of aesthesis and pain.

OUTCOMES MEASURES

The primary outcome was patient satisfaction regarding wound cosmesis and pain. Secondary outcomes were the cost of the procedure and wound complications.

PATIENTS

INCLUSION CRITERIA:

For selection of convenience patients more than 18 years of age who were going for operation for obstetric or gynaecologic procedure were included in the study. Emergency or elective procedures both were included in the study but all patients had Pfannenstiel incisions.

EXCLUSION CRITERIA

- Body mass index of more than 40
- Alcohol or drug abuse

- Refusal for follow up
- Diabetes
- Previous abdominal surgery

Patients with diabetes and BMI>40 were excluded as they are known risk factor for post operative wound complications. Patients undergoing operation were informed about the details of the study. Consent was requested before the operation. A consent and information form was signed. Baseline demographics and clinical data were collected.

SAMPLE SIZE

Initially one hundred women were randomised to receive surgical staples or subcuticular sutures with the intention to add more patients if needed for statistical power. This sample size was for convenience. Our results after 100 cases showed enough evidence and after consultation with a statistician we did not recruit any further patients.

JUSTIFICATION

Current data is not conclusive to determine the best method of wound closure [48-50]. Although studies were performed to compare various methods of wound closure, there is no conclusive consensus. This study highlights the patient satisfaction in terms of pain and cosmesis. The study was randomised and there was independent assessment of photographs by a blind observer. This added to the robustness of the findings.

CONFIDENTIALITY

Data was anonymous and participants will not be identified in any publication of the trial.

ETHICAL CONSIDERATIONS

The objectives and goals of the study were fully explained to the patient and informed consent was obtained. (Addendum 1) Good clinical Practice (GCP) guidelines (WHO1995) were followed. Confidentiality was assured to all the patients. Regular audit of procedures was done. Quality control of data management was done regularly. Data sheets and all other documents were stored for future reference, audits and queries. The protocol was approved by the Human Research Ethics Committee of Stellenbosch University and the project number is N10/09/295.

DURATION OF THE PROJECT

Recruitment stretched over eight months from December 2010 to August 2011.

METHODS

A computer generated random sequence was used. Randomization envelopes was prepared independently. The anaesthetist was informed about the study. He/she was asked to open the envelope to establish which method of wound closure should be used. The surgeon recorded the time taken for wound closure. Only Pfannenstiel incisions were included in the study. Subcutaneous fat was closed in a separate layer only if it was more than 2 cm thick.

Continuous subcuticular closure was done by using Polyglactin (vicryl) sutures. The suture was placed subcutically in a running fashion. Needle was placed in the dermis 1-2 mm from the wound edge. The needle was not passed through the skin surface. Mirror image bites were taken horizontally for the full length of the incision. Knots at the ends were buried under the skin. Great care was taken to avoid tension of the wounds.

Staples were used for the other method. For their application an assistant everted the skin edges and the stapler was placed firmly on the skin surface perpendicular to the wound. It was pressed firmly avoiding indenting of the skin. The centre mark on the stapler was aligned with the centre of the wound margin. The stapler was squeezed, plunging the staple into the skin to form an incomplete rectangle. The depth of the penetration depends on the pressure exerted on the stapler against the skin. To disengage the staple the handle was released.

If the stapler did not automatically release the staple, then the stapler was pulled back. The staples were placed about 1cm apart. Staples were removed on day 7 postoperatively. The incision was measured at the end of the procedure. Dressings were identical in both groups.

Patients were reviewed six weeks after the operation. In addition, a digital photograph was also taken and evaluated by a consultant. The consultant was blinded to the method of skin closure. Each photograph was evaluated for

discharge, keloid formation, hatch marks, any redness and separation of the wound edges. Patients were also asked about pain and cosmesis which was assessed on the scale of 1 to 5 . A simple pain scale was used. Where 1 means no pain, 2 means mild pain, 3 means moderate pain, 4 means severe pain and 5 means very severe pain (Addendum 2). Similarly patient satisfaction regarding cosmesis was assessed on a scale of 1 to 5 where 1 corresponds to extremely satisfied, 2 corresponds to satisfactory, 3 corresponds to neutral, 4 corresponds to not satisfied and 5 corresponds to extremely not satisfied (Addendum 2)

STATISTICAL ANALYSIS

Statistical analysis was performed by Prof Kidd, from the Dept of Statistics and Actuarial Sciences at Stellenbosch University. Analysis of variance was used to compare the two procedures in terms of ordinal measurements like patient satisfaction. Spearman correlations were used for determining relationships between ordinal measurements. Cross tabulation (with the Chi-square test) was used for comparison of categorical variables between the procedures like HIV status. Analysis of covariance was used to determine if age and BMI had any effect on comparisons of the outcome variables between the procedures.

RESULTS

A total of one hundred women were randomised. Only those patients who met the criteria were included in the study. These women were enrolled into the two

intervention groups (n=49) for the subcutaneous group compared to the staple (n=51). Eighty nine patients completed the study and complete data was available for final assessment. Eleven were lost to follow-up. Five were lost from the subcuticular groups and six from the staple group.

PATIENTS CHARACTERISTICS

These women in the trial groups had similar baseline and demographic details (see Table 1).

The patients were between 18 and 42 years of age. The median age was of 30 years.

	Subcuticular sutures	Staples	P value
Number (n)	49	51	
Maternal age (mean)	27	30	.91
Gynaecology (n)	6	11	
Obstetrics (n)	47	36	
HIV positive	8	6	.75

Table 1: Patient characteristics

There were only 18 patients who have gynaecological surgery as compared to 82 obstetrics patients. Therefore it was not advisable to do comparison between the two groups.

Patients underwent surgery for various reasons as shown in the following figure

1.

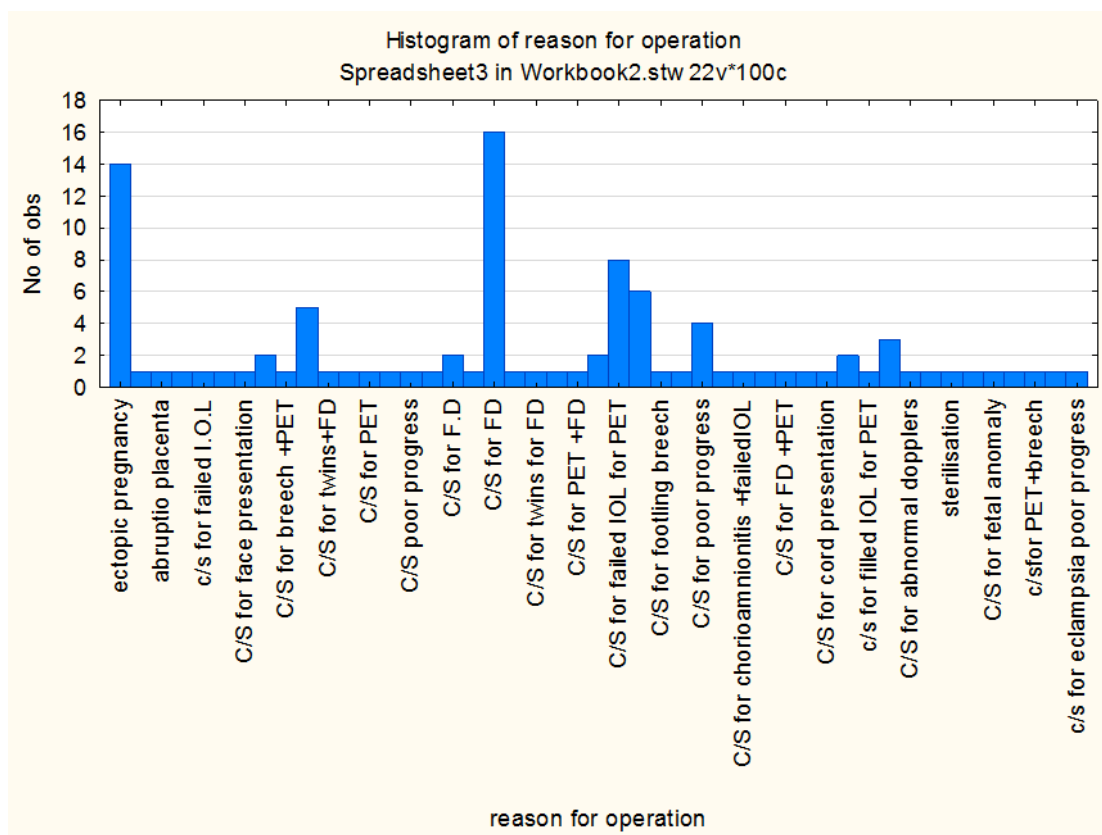


Figure 1. Reason of operation

There was no difference as regards the length of the incision of the patients randomised to the two methods of wound closure.

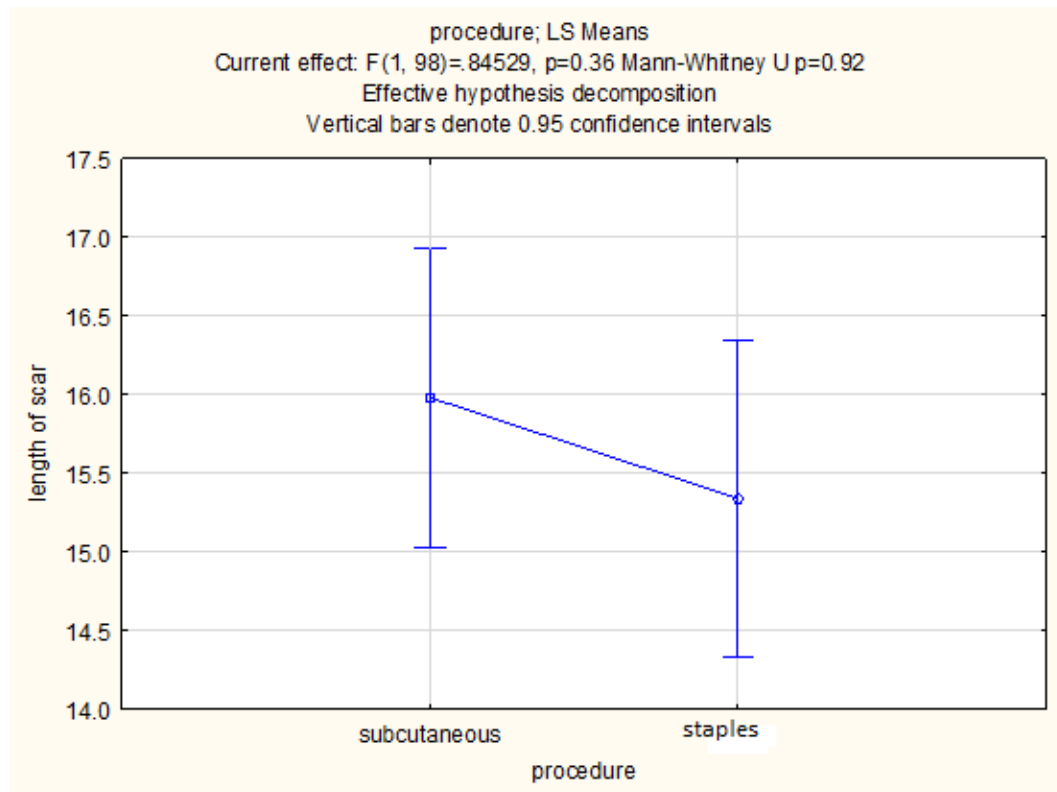


Figure 2. Length of Scar.

OUTCOMES: PATIENT SATISFACTION

Our study demonstrates no statistically significant difference regarding the patient satisfaction between the two groups subcuticular suture versus staple group ($P = 0.76$).

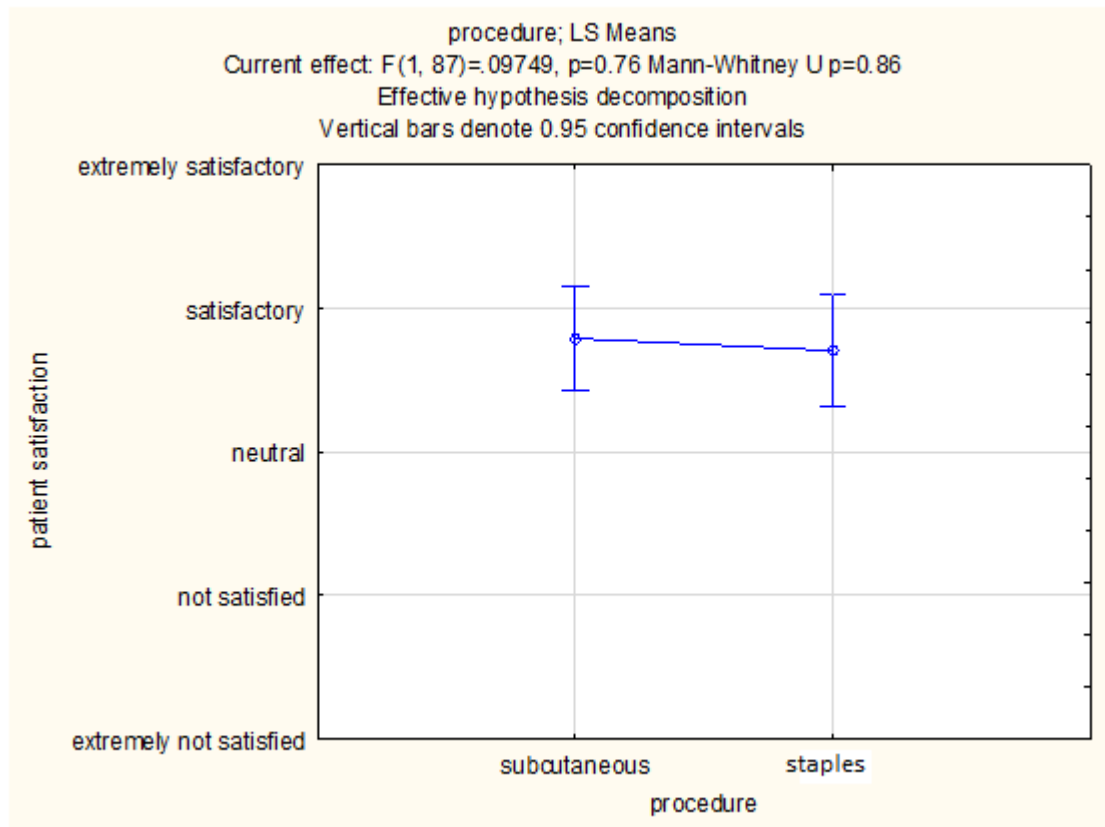


Figure 3. Patient satisfaction

There was no statistically significant difference in the two groups as regarding wound cosmesis.

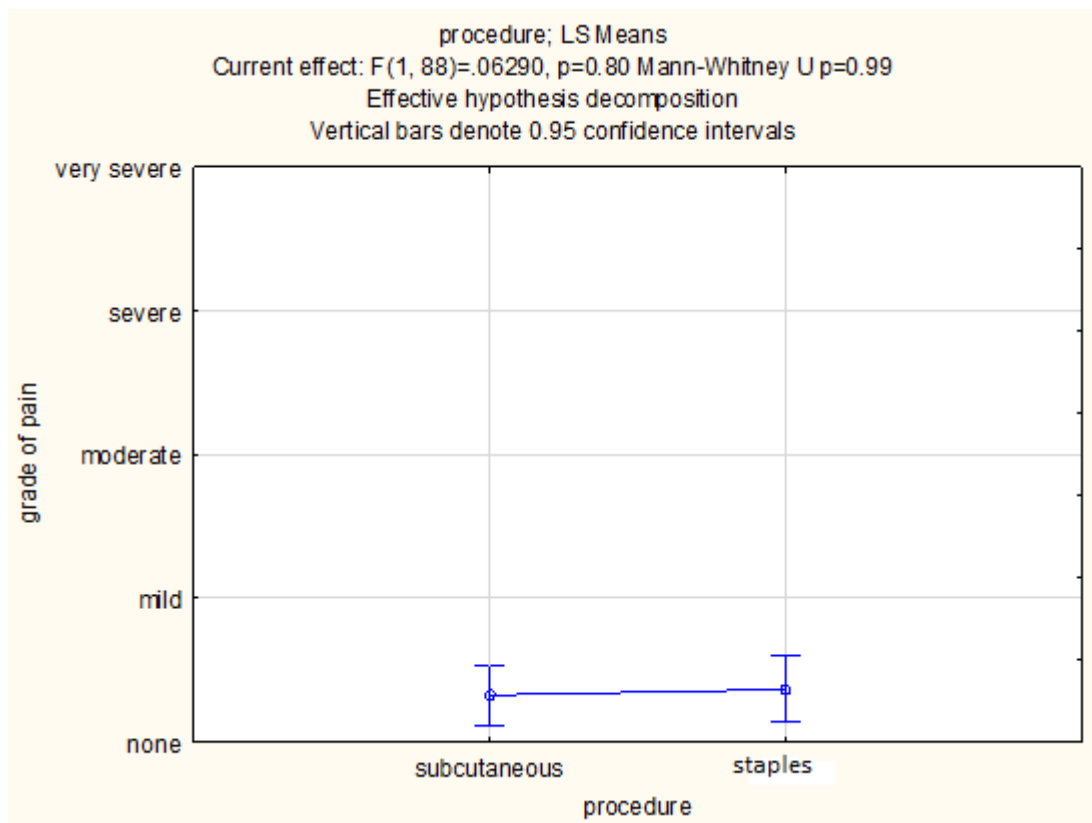


Figure 4. Grade of pain

The following table (Table 2) gives a good idea about the patient satisfaction and the observation by our blinded observer. They were all significantly correlated, meaning that high patient satisfaction was associated with high observer scores and vice versa.

Patient satisfaction variable	Spearman	Spearman p-value
Keloid formation (photo)	-0.57	<0.01
Colour redness (photo)	-0.43	<0.01
Separation of skin edges (photo)	-0.28	<0.01
Scars (photo)	-0.51	<0.01

Table 2. Indication of correlation between patient and blind observer scores.

As regards the pain described by the patients there was no statistically significant difference between the two groups ($P = 0.80$).

It was also noted that the HIV and increased BMI had no influence between the groups. There were only 14 HIV positive patients in the sample and they were evenly distributed between the groups ($p=0.93$). Patient satisfaction was also found not to have been influenced by HIV status ($p=0.75$). An analysis of covariance was conducted to determine if BMI had any effect on possible differences in patient satisfaction between the groups, but no significant difference was found ($p=0.81$).

Similar to BMI analysis of covariance also indicated that age did not affect the patient satisfaction results ($p=0.91$).

Mean time of closure was 3.5 minutes for the subcuticular group as compared to the 1.02 minutes for the staple group. This study demonstrates that staples can be applied at a much faster rate than the subcuticular stitches ($P < 0.01$).

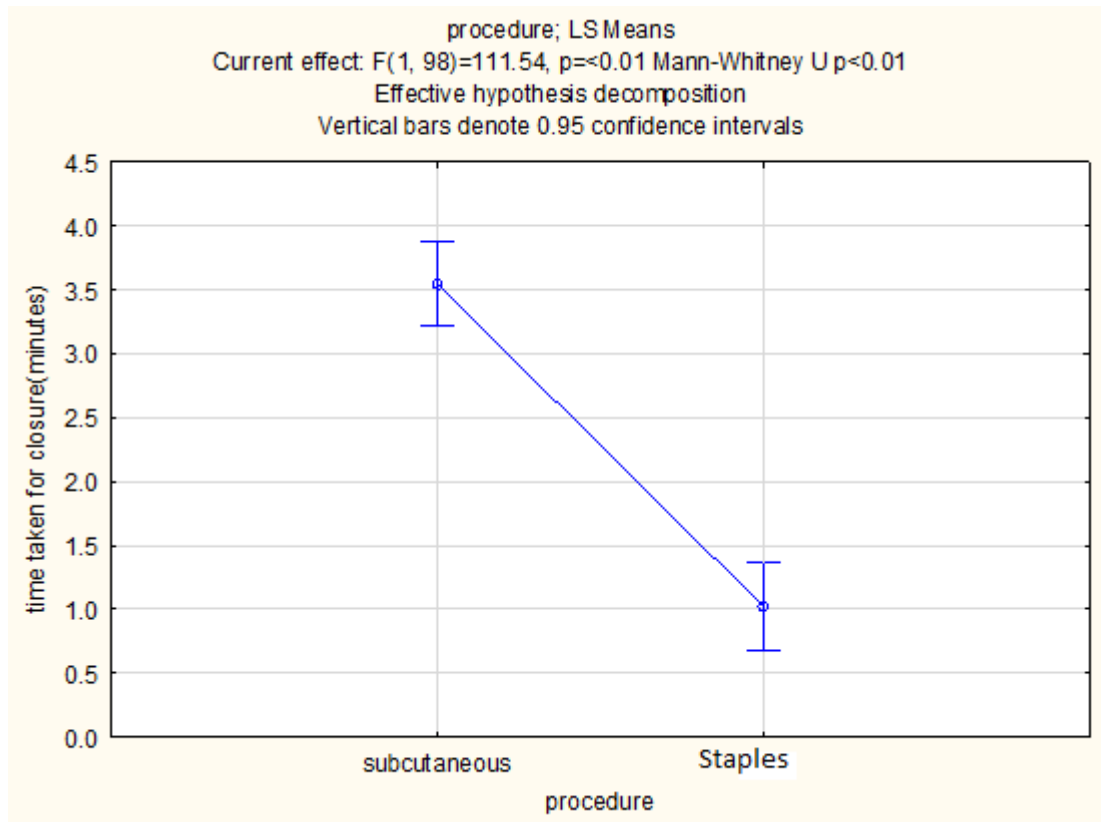


Figure 5. Time of closure

Despite the difference in the seniority of the surgeon there was no difference in the wound cosmesis and patient satisfaction. 25% of the operations were done by consultant, 50% by registrars and 24% by medical officer. See the figure 6.

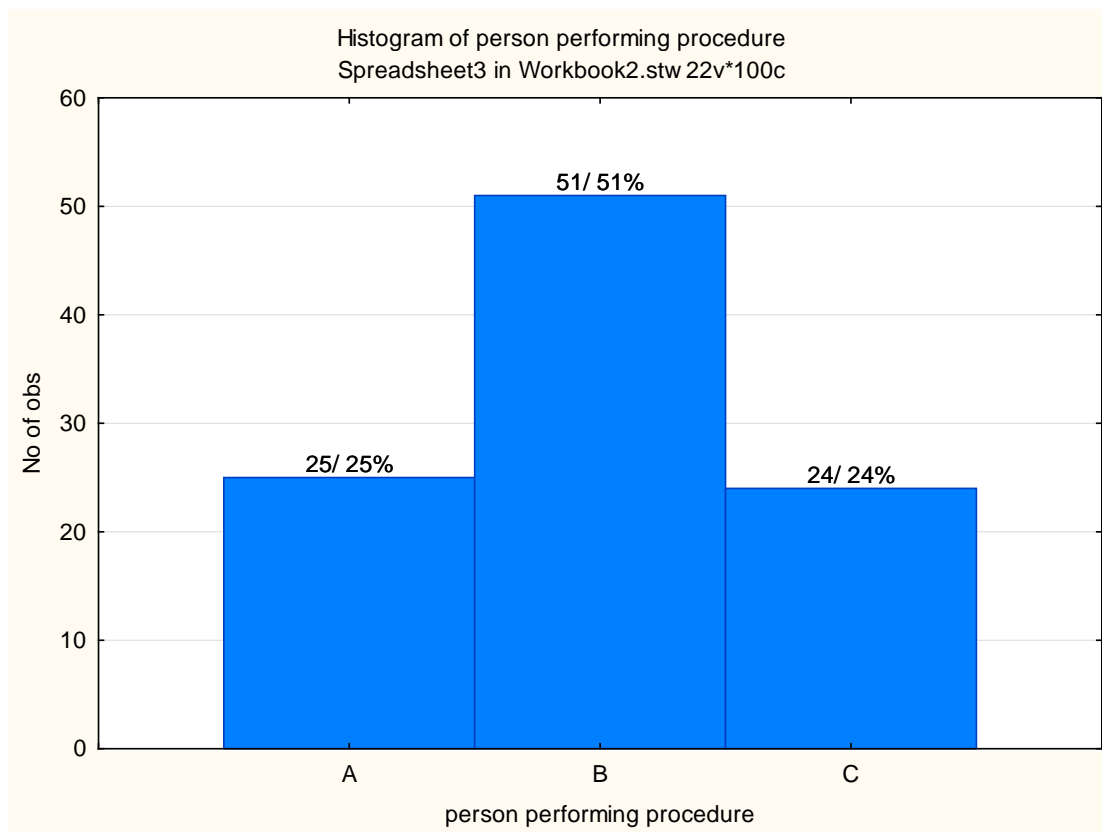


Figure 6. Person performing the procedure

There was only one patient who came with infection at six weeks. She had clips still in situ at six weeks. No other patient with wound complications like infection or hematoma formation.

Summarising this study suggest that the two methods of wound closure subcuticular suture versus staple have similar outcomes as regards the patient satisfaction for both the wound cosmesis and pain.

DISCUSSION

Considering the number of women who undergo operations for gynaecological and obstetrical indications around the world each year, the issue of appropriate method of wound closure is still poorly studied.

We decided to perform this study to support surgeons in making evidence – based decision about the best method of skin closure after abdominal surgery. The result of this study shows there was no clinically and statistically difference in the two methods of wound closure with regards to patient satisfaction. Patient satisfaction includes both the aesthetic effect of the scar and the degree of pain.

In a similar study Frishman et al [6] wound cosmesis was better in the subcuticular suture group than the staple group. The study was done on a small number of patients (n = 50) and no comment on blinding was made. The investigations may have been biased. They also found that patients had significantly more pain in the staple group.

In another study reported by Gaertner et al [8] the researcher were not blinded for the method of wound closure the same result about wound cosmesis was found. In our study we decided to add the opinion of a blind observer. Unbiased observation strengthened the clinical significance of the study.

In a study Rousseau et al [10] no significant difference in the appearance of the wound was found but pain was significantly less in the staple group. The

scientific explanation of this is not clear. The results of this study contradict the results of our study.

Cromi et al [12] also found no difference in patient satisfaction between the two groups staple vs. subcuticular sutures. They never assessed pain which also forms an important part of the patient's satisfaction. They assessed patients at 2 months and at six months.

In a study done by Basha et al [13] it was reported that patients were less satisfied with staples because of wound complications and their sequelae. Wound complications were 4 fold more in the staple group when compared to the subcuticular group. But when they controlled for the wound complications they found no difference in the patient satisfaction in both the groups i.e. staple vs. subcuticular group.

One of the important and essential aspects of the patient satisfaction is assessment of pain. Simple factors like overwork and social stresses can make considerable difference. Also the magnitude, cause and management of pain are important.

It is evident from all the studies reviewed that staples are quick to apply. From the surgeon's point of view it is a quick, easy and safe method as it also decreases the risk of needle stick injuries. From the management point of view it decreases theatre time and perhaps also the cost of the procedure. But we must keep in mind that the staples are far more expensive and availability is also

an issue. Moreover the best time to remove the staples is at day 7- 10 days. According to available literature the inflammatory process continues beyond the seven days. This is very important point to note as the skin seems intact within days after the injury, but the tissues underneath are still vulnerable to damage and may not be strong enough to withstand daily tensile forces.

In South Africa we must consider the socioeconomic circumstances of patients. The patient has to come for another visit. Nursing personnel has to be present and they require a special instrument to remove the staples. All this adds to the cost and are burdensome to the patient.

The statistically significant difference of the decrease in the operating time does not seem to be of so much significant clinically especially in elective surgery as it forms only small part of the overall surgical time. In case of emergency surgery the preference to the use of staple still has to be evaluated.

Loss to follow up is one of the biggest challenges of prospective studies. To minimise this women were followed up by a single observer and they were asked to come to hospital for the photograph. However, if for any reason they could not come they were interviewed telephonically and were asked to send photographs via MMS. The reasons for lost of follow up is predominantly the increase demands to settle in the post partum period and to attend to their household responsibilities

LIMITATIONS

Our study only included patients who were not operated before and more studies need to be done to study women who have a previous scar. We excluded diabetics and the patients with BMI > 40 which can significantly influence the process of wound healing.

Patients are followed up at six weeks only. Some wound complications can such as incisional hernia or keloid can develop much later. Full healing may take months but no major difference appears regarding the cosmesis after six weeks.

RECOMMENDATIONS

Taking our results into consideration, we cannot recommend any specific type of skin closure.

This leaves the choice of the appropriate method of wound closure in the hands of the surgeon according to his own personnel choice and the availability of the suture material at that time.

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PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT: Randomised Trial to compare patient satisfaction for wound closure: Surgical clips compared to subcutaneous sutures

REFERENCE NUMBER:

PRINCIPAL INVESTIGATOR: Dr Mahnaz Kalim

ADDRESS: Department of Obstetrics and Gynaecology, Tygerberg Hospital.

CONTACT NUMBER: 0824234925

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee (HREC) at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

- The research will be conducted at Tygerberg Hospital. A total of 100 women will be invited to take part in the study.
- The aim of the research is to improve patient care by finding out which is the best method of wound closure. One group of women will be selected randomly to have their wounds closed with sutures (stitches) underneath the skin. The other group will get small surgical staples (clips) to close the wound. Both methods are widely used but we do not yet know which of these will give the least discomfort after the operation or the best cosmetic outcome.
- All women undergoing gynaecological operations are invited to take part in the study.
- The benefit of this research is that it may help to decide which the best method of wound closure is.
- There are no risks involved.
- The information collected will be treated as confidential. If it is used in a publication or thesis, the identity of the participants will remain anonymous.

- You will not receive any payment to take part in the study but it will also not cost anything. There are no extra visits to the hospital and no additional blood tests.
- You can contact Dr Mahnaz Kalim at tel 0824234925 if you have any further queries or encounter any problems.
- You can contact the **Health Research Ethics Committee** at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I agree to take part in a research study entitled (*insert title of study*).

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) on (*date*) 2010.

.....
Signature of participant

.....
Signature of witness

Declaration by investigator

I (*name*) declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above

- I did/did not use a interpreter. *(If an interpreter is used then the interpreter must sign the declaration below.*

Signed at (*place*) on (*date*) 2010

.....
Signature of investigator

.....
Signature of witness

Declaration by interpreter

I (*name*) declare that:

- I assisted the investigator (*name*)
to explain the information in this document to (*name of participant*)
..... using the language medium of
Afrikaans/Xhosa.
- We encouraged her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*) on (*date*)

.....
Signature of interpreter Signature of witness

DATA COLLECTION SHEET

Serial Number			Date of Operation		Follow up Date
Name					
Age			Phone Number		
Address					
Indication of Operation					
Risk Factors					
HIV	CD4	BMI	Previous Operation	Use Antibiotics	of Other
Surgeon		Procedure		Time	
Length of Scar(cm)					
Grade of Pain					
None	mild	moderate	severe	Very severe	
Patient Satisfaction Regarding Cosmesis					
Extremely Satisfactory		Satisfactory	Neutral	Not satisfied	Extremely not satisfied
Discharge(Photograph)					
1	2	3	4	5	
Keloid Formation(Photograph)					
1	2	3	4	5	
Colour Redness(photograph)					
1	2	3	4	5	
Separation of Skin(photograph)					
1	2	3	4	5	
Scars(photograph)					
1	2	3	4	5	